

REMARKS

This paper is filed in response to an Office action mailed on March 29, 2007. In that Office action, claims 1, 4, 6, 10, 13, 16, and 18 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 4,168,703 ("Kenigsberg"); and claims 7, 14, and 19 are rejected under 35 U.S.C. 103(a) as being obvious over Kenigsberg in view of U.S. Patent No. 6,259,938 ("Zarychta"). In response, Applicant has hereby cancelled claims 1, 4, 6-7, and 18, without prejudice, and amended claims 10 and 16. By way of this amendment, Applicant respectfully submits that none of the amended set of claims presented herein is obvious over the cited references because a *prima facie* case of obviousness cannot be established with the modification or combination of the cited references proposed by the Examiner.

Claim Rejections – 35 U.S.C. 103

As claims 1, 4, 6-7, and 18 are cancelled without prejudice, the claims presented herein and at issue are independent claims 10 and 16, and dependent claims 13-14, and 19. By way of this amendment, Applicant respectfully submits that each of the amended set of claims includes one or more limitations that cannot be reached by the modification or combination of the cited references proposed by the Examiner. Accordingly, the obviousness rejections are traversed and should be withdrawn.

With respect to the independent claim, Applicant submits that amended claims 10 and 16 presented herein are not obvious over Kenigsberg because both claims now specify a device having a distal portion with an exterior surface having a cross-sectional profile of a single circle, wherein the device comprises, among other things, a tubular sheath having an inside *peripheral* surface, and an elongated tube received within the tubular sheath and having an outside *peripheral* surface engaging the inside peripheral surface of the sheath about the entire outside peripheral surface of the elongated tube. Applicant further submits

that such a device is not obvious over Kenigsberg because a *prima facie* case of obviousness cannot be established. Under MPEP § 2142,

"[t]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." *Citing, In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991); *see also* MPEP § 2143-§ 2143.03 for decisions pertinent to each of these criteria.

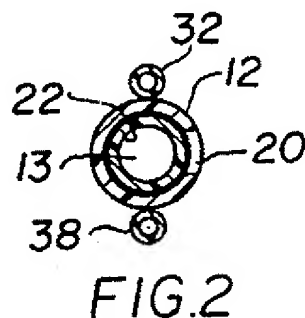
In the Office action, the Examiner asserts that Kenigsberg discloses a diagnostic device having a distal portion with an exterior surface having a cross-sectional profile of a single circle, wherein the device comprises, among other things, a tubular sheath having an inside surface, and an elongated tube having a outside surface and slidably received in the tubular sheath so that fluid communication through the tubular sheath between the inside surface of the tubular sheath and the outside surface of the elongated tube is prevented.

Contrary to the Examiner's assertion, Applicant respectfully submits that Kenigsberg's device does not have a distal portion with an exterior surface having a cross-sectional profile of a single circle as recited in amended claims 10 and 16 because Kenigsberg's device includes an elongated tubular reference member (32) extending substantially the length of the outer sheath (12) and terminating in an end adjacent to the distal end of the tubular sheath (col. 3, lines 57-67). Throughout the specification and drawings, Kenigsberg discloses the positioning of the reference member (32) on the surface of the sheath. Such positioning, however, clearly renders the distal portion of Kenigsberg's

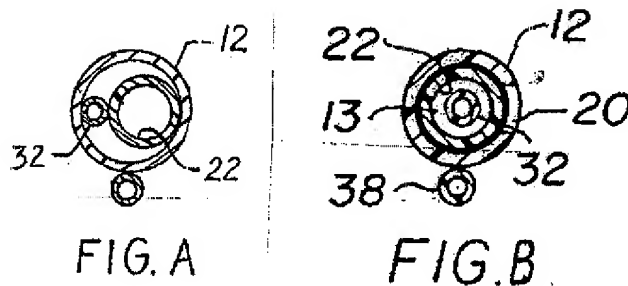
device having a non-circular cross-sectional profile, as opposed to the circular cross-sectional profile recited in amended claims 10 and 16.

Presumably realizing this deficiency, the Examiner further asserts, in the Response to Argument section of the Office action, that “Kenigsberg discloses positioning the reference member (32) within the outer sheath (12)”, and “[t]hus the distal portion of the measuring device includes an exterior surface having a cross-sectional profile of a single circle.”

Applicant, however, respectfully disagrees. Although Kenigsberg discloses that “the member 32 may be located within a suitably modified sheath (not shown) provided its placement within the sheath does not interfere with the free movement of the probe 22 therein” (col. 3, lines 61-65, emphasis added), it does not teach or suggest the positional relationship between the reference member (32) and the probe (22), both of which are now disposed within the sheath (12), nor does it teach or suggest how to modify the sheath to accommodate such positioning. Moreover, Applicant hereby submits that notwithstanding the Examiner’s assertion to the contrary, such positioning can only be accommodated by suitably modifying the shape of the sheath to adopt a noncircular cross-sectional profile at the distal portion thereof. The cross-sectional profile of Kenigsberg’s device is illustrated in FIG. 2, a copy of which is attached below for reference purposes.



Assuming, hypothetically, that the reference member (32) is to be positioned within the sheath (12) without changing the circular cross-sectional profile thereof, only two possible configurations would be available to accommodate such positioning: a side-by-side configuration wherein the reference member (32) is positioned alongside the probe (22) as illustrated in FIG. A below; and a concentric configuration wherein the reference member (32) is disposed within the interior of the probe (22) as illustrated in FIG. B below.



Both of those configurations, however, would either vitiate one or more limitations recited in amended claims 10 and 16, or render Kenigsberg's device inoperable, and therefore cannot serve as proper modifications of Kenigsberg to render the subject matter specified in amended claims 10 and 16 obvious.

More specifically, in the side-by-side configuration, the inclusion of the reference member (32) within the interior of the sheath (12) alongside the probe (22) would render the engagement between the outside peripheral surface of the probe and inside peripheral surface of the sheath recited in amended claims 10 and 16 geometrically impossible. Therefore, this modification of Kenigsberg's device cannot render the amended independent claims obviousness because it fails to teach each and every limitation recited in

amended claims 10 and 16, and therefore at least the third criterion of a *prima facie* case of obviousness is not met.

The concentric configuration, on the other hand, is not a viable modification because such modification renders Kenigsberg's device inoperable. Consequently, there cannot be any suggestion or motivation for this modification, and therefore at least the first criterion of a *prima facie* case of obviousness is not met. Applicant respectfully submits that the inclusion of the reference member (32) in Kenigsberg's device is for continuous measuring of the pressure inside the stomach as a real-time reference to the pressure of the gastroesophageal track measured by the elongated tube (22) when the elongated tube moves along the track.

Such operating mechanism, however, is clearly incompatible with the concentric configuration illustrated in FIG. B because the reference member, when disposed within the interior of the elongated member having a closed end (see Office action), cannot be in constant contact with the inside of the stomach as the elongated tube moves along the track, and therefore cannot continuously measure the pressure of same. Consequently, there can be no suggestion or motivation for modifying Kenigsberg according to the concentric configuration because under MPEP 2143.01, "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See also *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

As neither configuration can establish a *prima facie* case of obviousness for claims 10 and 16, it is submitted that no modification of Kenigsberg's device can render subject matter specified in the amended independent claims obvious, unless the cross-sectional profile of the sheath (12) is also modified. Such modification, however, would

render the exterior surface of Kenigsberg's device having a noncircular cross-sectional profile, and therefore cannot teach all limitations recited in amended claims 10 and 16 as well.

Thus, as one of ordinary skill in the art cannot properly modify Kenigsberg's device to include each and every limitation recited in amended claims 10 and 16, Applicant respectfully submits that amended claims 10 and 16 are not obvious over Kenigsberg because a *prima facie* case of obviousness cannot be established. Accordingly, the obviousness rejection on independent claims 10 and 16 are overcome and should be withdrawn.

Turning to the dependent claims In the outstanding Office action, claim 13 is rejected as being obvious over Kenigsberg; and claims 14 and 19 are rejected as being obvious over Kenigsberg in view of Zarychta Applicant respectfully submits that those rejections are overcome by way of this amendment because neither modification of Kenigsberg or combination of Kenigsberg with Zarychta can render the amended independent claims obvious. It follows that the dependent claim depended thereon cannot be rendered obvious by same as well.

As discussed above, modification of Kenigsberg proposed by the Examiner cannot render the amended independent claims obvious because a *prima facie* case of obviousness cannot be established by the modification. Applicant further submits that the combination of Kenigsberg with Zarychta cannot render the amended independent claims obvious as well.

Zarychta discloses a monitoring catheter for detecting various signals along a gastroesophageal track of a patient, wherein the catheter comprises a plurality of side-by-side lumens therein, and a radiopaque material disposed at a distal end thereof. Applicant

respectfully submits that Zarychta is merely cited by the Examiner for the purpose of its disclosure of providing a radiopaque material at the distal end of the catheter, and therefore adds nothing to the deficiency of Kenigsberg discussed above

Moreover, although Zarychta discloses the provision of two pressure ports on the catheter wall, each connected to a separate lumen for simultaneous measurement of pressure, it does not teach or suggest the provision of a slidable elongated member within the catheter, much less an elongated member having an outside peripheral surface engaging the inside peripheral surface of the catheter about the entire outside peripheral surface of the elongated member, and therefore adds nothing to the deficiency of the side-by-side configuration discussed above.

Thus, neither the modification of Kenigsberg nor the combination of Kenigsberg and Zarychta proposed by the Examiner renders amended claims 10 and 16 obvious. It follows that the dependent claims dependent thereon, *i.e.* claims 13-14, and 19, cannot be rendered obvious by same. Applicant therefore respectfully submits that the obviousness rejections of the dependent claims 13-14, and 19 are overcome because a *prima facie* case of obviousness cannot be established with the modification or combinations of cited references suggested by the Examiner.

In light of all the foregoing, Applicant respectfully submits that each of the currently pending claims is in a condition for allowance and respectfully solicits same. If a telephone call would expedite prosecution of the subject application, the Examiner is invited to call the undersigned attorney

Dated: June 4, 2007

Respectfully submitted,

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